

K161026 NexSite™ HD Hemodialysis Step Tip Catheter For Long Term Use (24 cm, 28 cm, 32 cm, 36 cm, 40 cm, 55 cm)Aug 9, 2016
119 days to decisionK161026 · Product code: **MSD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k161026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Apr 12, 2016
Decision date	Aug 9, 2016
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Marvao Medical Devices, Ltd.
Location	Northborough, MA, US
Contact	Christopher Davey
510(k) history	9 submissions · 4 cleared · 2011-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161026/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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